

## **APPENDIX A -- National Expert Panel**

- Heidi Anderson-Harper, PhD, RPh (AL)  
– pharmacy educator/researcher with expertise in the design and evaluation of drug information materials for persons with diverse social backgrounds and medical conditions
- Robert Beardsley, PhD, RPh (MD)  
– pharmacy educator/researcher with expertise in communications research and education
- CA Bond, PharmD (TX)  
- pharmacy educator/researcher with expertise in therapeutics and evaluation of pharmacy services; has evaluated the cost-effectiveness of pharmacy-based informational services that he and his colleagues designed and implemented for their patients; continues to practice pharmacy
- Marie Gardner, PharmD (AZ)  
- pharmacy educator/researcher with expertise in therapeutics and patient counseling; helped develop videotapes and educational materials for community pharmacists in the area of patient consultation.
- Carole Kimberlin, PhD (FL)  
-educational psychologist with expertise in communications and measurement; has designed and evaluated informational services provided by community pharmacists
- Duane Kirking, PhD, PharmD (MI)  
- pharmacy educator/researcher with broad expertise in drug information, statistical analysis, and evaluation techniques
- Sharlea Leatherwood, RPh (MO)  
- community pharmacist, past president of Missouri Board of Pharmacy
- Helene Lipton, PhD (CA)  
– medical sociologist with expertise in social scientific methods of research and evaluation, especially the use of expert panels and reliability testing; has designed and evaluated pharmacy-based informational services for elderly persons
- Betsy Sleath, PhD, RPh (NC)  
– pharmacy educator/researcher with expertise in “content analysis” and other techniques for evaluating the quality of information provided to patients by physicians and pharmacists

## APPENDIX B

| Questions Commonly Asked in Pharmacy                                       | Patient-Observer Answers  |
|--|---|
| Hello, can I help you?   | Yes, would you fill these prescriptions for me.   |
| Have you filled prescriptions here before?                                 | No.   |
| What is your name?   | (assigned name)   |
| What is your birth date?   | (Your birthdate)  |
| What is your address?  | (assigned or your own address)  |
| Are you visiting?  | Yes, I am.  |
| What is your telephone number?   | (assigned or your own telephone number)   |
| How will you pay for the prescriptions?                                    | I will pay with cash.   |
| Do you have prescription insurance?  | Yes, I am covered by Blue Cross/Blue Shield.<br>I submit my receipts for reimbursement. |
| Do you have any other medical conditions?                                  | No, I am basically healthy.   |
| Do you take any other prescription medications?                            | No, I am not taking any other medications.  |
| Do you have any allergies to medications?                                  | No, none that I know of.  |
| Have you been taking any over-the-counter or non-prescription medications? | No, I haven't been taking any medications.  |
| Is this the first time you have taken any of these medications?            | Yes, it's the first time I've taken any of these.                                       |
| What did the doctor tell you about the medications?                        | Just that the directions would be on the label.   |
| When are you talking with the doctor next?                                 | I will be seeing the doctor in a week.  |
| What will you do if you have any problems with the medication?             | I will call my doctor.  |
| What will you do if your health does not improve?                          | I will call my doctor.  |

## Appendix B (cont.)

| Questions Commonly Asked                                       | Patient-Observer Answers  |
|--|---|
| For what reason did the doctor prescribe amoxicillin?          | Sinus congestion. (If pressed, say the doctor said it is a sinus infection).                          |
| For what reason did the doctor prescribe ibuprofen?            | For my knees. (If pressed for more information say tendinitis of the knee).                           |
| For what reason did the doctor prescribe Paxil® or paroxetine? | I haven't been sleeping very well and I have been down. (If pressed say, the doctor said depression). |
| Have you had any other symptoms?                               | Just that I feel very tired.  |
| Would you like the pharmacist to counsel you?                  | Sure  |
| Would you like written information about the medication?       | Sure  |

## Appendix C –

Ibuprofen      No Form ‘

Pharmacy ID: \_ \_ \_      Rater ID: \_ \_

### Patient Information Evaluation Form

**Raters:** Please use check lists and rating scales to evaluate how well patient information meets each criterion.

**Rating scale:** disagree (1-3); equivocal (4-6); agree (7-9). Note: When evaluating written information, a guideline may be addressed fully (X) or partially (/).

To receive rating of agree (7-9) 100% of boxes must have a partial or full check; rating of equivocal (4-6) 50 - 99% of boxes with partial or full checks; and disagree (1-3) less than 50% of boxes with partial or full check.

1 - 3 = < 50% of boxes checked, if at all

4 - 6 = 50 - 99% of boxes checked, partial or full

7 - 9 = 100% boxes checked, partial or full

| <i>Criteria for evaluating usefulness of written information</i>  | Rating                          |
|---|---------------------------------|
| <b>1. Written information identifies drug and its benefits.</b><br>‘ generic (ibuprofen) and brand name (if dispensed a brand name, ex., Motrin), phonetic spelling<br>‘ used to relieve mild to moderate pain; pain, stiffness and swelling assoc w/ rheumatoid arthritis, osteoarthritis, and primary dysmenorrhea; also reduces fever<br>‘ drug class (nonsteroidal anti-inflammatory drug, often abbreviated NSAID)   | 1 2 3 4 5 6 7 8 9               |
| <b>2. Information includes specific directions about how to take medication, receive maximum benefit and interpret benefits.</b><br>‘ take with meals or milk to minimize GI effects; take with liquid; may combine with antacids<br>‘ if taken for arthritis, take regularly as prescribed; pain relief occurs w/in hour but anti-inflammatory effect occurs after 1-2 weeks of dosage<br>‘ take missed dose ASAP; skip if almost time for next dose   | 1 2 3 4 5 6 7 8 9<br>adequate   |
| <b>3. Information identifies contraindications and what to do if applicable.</b><br>‘ do not take if allergic to aspirin or other NSAID example, indomethacin, naproxen<br>‘ make sure provider knows about other medical problems that may affect use of ibuprofen, especially: ulcer disease, heart disease, pressure, kidney or liver dysfunction, coagulation defects /use of anticoagulants, impending surgery<br>‘ check with provider if pregnant or nursing; not to be used in children under 6 months of age         | 1 2 3 4 5 6 7 8 9<br>high blood |
| <b>4. Information includes specific precautions while using medicine, their significance, and how to avoid harm.</b><br>‘ not recommended to combine with aspirin because there is no known benefit<br>‘ long term use without proper monitoring should be avoided; patients at risk for kidney problems are those with impaired kidney function, heart failure, liver dysfunction, those taking diuretics and the elderly<br>‘ use caution when taking other OTC products that contain ibuprofen, do not exceed 3200mg daily | 1 2 3 4 5 6 7 8 9               |

|  |                   |
|--|-------------------|
| <p><b>5. Information includes enough detail for proper monitoring and interpretation of serious or frequently occurring adverse reactions.</b></p> <ul style="list-style-type: none"> <li>' stop taking and call provider immediately if: severe GI effects occur for ex., bleeding, ulceration, black or bloody stools; effects may result in hospitalization, may be fatal</li> <li>' tell provider about rash, if other side effects do not go away or are bothersome, incl: GI disturbances , blurred vision, weight gain or water retention</li> <li>' other side effects may occur, check with provider</li> </ul> | 1 2 3 4 5 6 7 8 9 |
| <p><b>6. Information includes proper storage instructions and general information.</b></p> <ul style="list-style-type: none"> <li>' store at room temperature, away from excess heat or moisture and away from children</li> <li>' includes disclaimer that this leaflet does not contain all possible information, provider can give additional information</li> <li>' includes information stating that medicine should only be used by patient and not given to others, may request non-child resistant caps</li> </ul>   | 1 2 3 4 5 6 7 8 9 |
| <p><b>7. Written information is unbiased in content and tone.</b></p> <ul style="list-style-type: none"> <li>' neutral in content and tone</li> <li>' does not contain promotional messages about product or compare to other brands (may compare chemical entities)</li> <li>' fair balance re benefits/risks</li> </ul>  | 1 2 3 4 5 6 7 8 9 |
| <p><b>8. Information is legible and readily comprehensible to most consumers.</b></p> <ul style="list-style-type: none"> <li>' written clearly; avoids long sentences; avoids or explains polysyllabic terms</li> <li>' layout calls attention to or makes it easy to locate important information, for ex., bullets, brief reinforcement separate from main text, headings, bold-face type or box</li> <li>' printed in 10-point type or larger (this is 10-point type), w/ upper and lower case letters, good contrast, and adequate space between lines and paragraphs</li> </ul>                                     | 1 2 3 4 5 6 7 8 9 |
| <p><b>9. Written information is scientifically accurate.</b></p> <ul style="list-style-type: none"> <li>' indication for use consistent w/ FDA labeling: relieves mild to moderate pain; pain, stiffness and swelling associated with rheumatoid arthritis, osteoarthritis, and primary dysmenorrhea</li> <li>' notes that medication may be used for other purposes; communication with provider is encouraged</li> <li>' general guide does not include information about non approved uses</li> </ul>   | 1 2 3 4 5 6 7 8 9 |
| <p><b>10. Information is up-to-date and timely.</b></p> <ul style="list-style-type: none"> <li>' includes publisher name and date of publication (not date printed for prescription use) or most recent revision</li> <li>' any additional information is consistent with current FDA approved labeling or federally recognized compendia</li> </ul>   | 1 2 3 4 5 6 7 8 9 |

1 - 3 = < 50% of boxes checked, if at all      4 - 6 = 50 - 99% of boxes checked, partial or full      7 - 9 = 100% boxes checked, partial or full

Revised: July 15, 1999

## APPENDIX C (cont.)

Amoxicillin      No Form '

Pharmacy ID: \_ \_ \_      Rater ID: \_ \_

### Patient Information Evaluation Form

**Raters:** Please use check lists and rating scales to evaluate how well patient information meets each criterion.

**Rating scale:** disagree (1-3); equivocal (4-6); agree (7-9). Note: When evaluating written information, a guideline may be addressed fully (X) or partially (/).

To receive rating of agree (7-9) 100% of boxes must have a partial or full check; rating of equivocal (4-6) 50 - 99% of boxes with partial or full checks; and disagree (1-3) less than 50% of boxes with partial or full check.

1 - 3 = < 50% of boxes checked, if at all

4 - 6 = 50 - 99% of boxes checked, partial or full

7 - 9 = 100% boxes checked, partial or full

| <i>Criteria for evaluating usefulness of written information</i>   | Rating            |
|--|-------------------|
| <b>1. Written information identifies drug and its benefits.</b><br>' generic (amoxicillin) and brand name (when dispensed a brand of amoxicillin, ex., Amoxil, Trimox), phonetic spelling<br>' drug class (penicillin antibiotic)<br>' used to treat bacterial infection, incl: respiratory, urinary, skin, venereal; not for common cold, flu, other virus infections     | 1 2 3 4 5 6 7 8 9 |
| <b>2. Information includes specific directions about how to take medication, receive maximum benefit, and interpret benefits..</b><br>' works best if taken at evenly spaced times, do not miss doses<br>' take missed dose ASAP; skip if almost time for next dose<br>' take with liquid and with or without food<br>' finish medicine even if feel better in a few days  | 1 2 3 4 5 6 7 8 9 |
| <b>3. Information identifies contraindications and what to do if applicable.</b><br>' do not take if allergic to amoxicillin or other penicillins and cephalosporins<br>' check with provider if pregnant or nursing; make sure provider knows about other medical problems  | 1 2 3 4 5 6 7 8 9 |
| <b>4. Information includes specific precautions while using medicine, their significance, and how to avoid harm.</b><br>' oral contraceptives may not work properly, use additional methods<br>' diabetic urine tests may be affected, check with provider before changing diet or diabetes medication; other medical tests may be affected,<br>tell provider before tests | 1 2 3 4 5 6 7 8 9 |

|  |                   |
|--|-------------------|
| <b>5. Information includes enough detail for proper monitoring and interpretation of serious or frequently occurring adverse reactions.</b><br>' stop taking and call provider immediately if: severe skin rash, hives, or itching; difficulty breathing or swallowing; severe diarrhea or stomach cramps<br>' tell provider if side effects do not go away or are bothersome, incl: mild skin rash, upset stomach and mild diarrhea<br>' other side effects may occur, check with provider                        | 1 2 3 4 5 6 7 8 9 |
| <b>6. Information includes proper storage instructions and general information.</b><br>' store at room temperature, away from excess heat or moisture and away from children<br>' includes disclaimer that this leaflet does not contain all possible information, provider can give additional information<br>' includes information stating that medicine should only be used by patient and not given to others; may request non-child resistant caps   | 1 2 3 4 5 6 7 8 9 |
| <b>7. Written information is unbiased in content and tone.</b><br>' neutral in content and tone<br>' does not contain promotional messages about product or compare to other brands (may compare chemical entities)<br>' fair balance re benefits/risks  | 1 2 3 4 5 6 7 8 9 |
| <b>8. Information is legible and readily comprehensible to most consumers.</b><br>' written clearly; avoids long sentences; avoids or explains polysyllabic terms<br>' layout calls attention to or makes it easy to locate important information, for ex., bullets, brief reinforcement separate from main text, headings, bold-face type or box<br>' printed in 10-point type or larger (this is 10-point type), w/ upper and lower case letters, good contrast, and adequate space between lines and paragraphs | 1 2 3 4 5 6 7 8 9 |
| <b>9. Written information is scientifically accurate.</b><br>' indication for use consistent w/ FDA labeling: treats bacterial infection, incl: respiratory, urinary, skin, venereal<br>' encourages communication with provider about the use of this medicine<br>' general guide does not include information about non approved uses  | 1 2 3 4 5 6 7 8 9 |
| <b>10. Information is up-to-date and timely.</b><br>' includes publisher name and date of publication (not date printed from prescription use) or most recent revision<br>' any additional information is consistent with current FDA approved labeling or federally recognized compendia  | 1 2 3 4 5 6 7 8 9 |

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## APPENDIX C - (cont)

Paroxetine No Form ‘

Pharmacy ID: \_ \_ \_ Rater ID: \_ \_

### Patient Information Evaluation Form

**Raters:** Please use check lists and rating scales to evaluate how well patient information meets each criterion.

**Rating scale:** disagree (1-3); equivocal (4-6); agree (7-9). Note: When evaluating written information, a guideline may be addressed fully (X) or partially (/).

To receive rating of agree (7-9) 100% of boxes must have a partial or full check; rating of equivocal (4-6) 50 - 99% of boxes with partial or full checks; and disagree (1-3) less than 50% of boxes with partial or full check.

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7 - 9 = 100% boxes checked, partial or full

| <i>Criteria for evaluating usefulness of written information</i>   | Rating            |
|--|-------------------|
| <b>1. Written information identifies drug and its benefits.</b><br>‘ generic (paroxetine) and brand (Paxil) names, phonetic spelling<br>‘ drug class (antidepressant); selective serotonin re-uptake inhibitor often abbreviated as SSRI<br>‘ used to treat depression, obsessive-compulsive disorder and panic disorder   | 1 2 3 4 5 6 7 8 9 |
| <b>2. Information includes specific directions about how to take medication, receive maximum benefit, and interpret benefits.</b><br>‘ take same time daily, do not miss dose<br>‘ take missed dose ASAP; skip if almost time for next dose<br>‘ may notice improvement in 1 to 4 wks, but generally is continued for several months or longer; talk w/ provider about treatment length<br>‘ take with liquid and with or without food   | 1 2 3 4 5 6 7 8 9 |
| <b>3. Information identifies contraindications and what to do if applicable.</b><br>‘ do not start paroxetine and check with provider if currently taking a Monoamine Oxidase Inhibitor (MAOI) ie phenelzine (Nardil) or tranylcypromine (Parnate)<br>‘ make sure provider knows about previous medical problems because may affect use of paroxetine<br>‘ check with provider if pregnant or nursing; safety and efficacy in pediatric population has not been established  | 1 2 3 4 5 6 7 8 9 |
| <b>4. Information includes specific precautions while using medicine, their significance, and how to avoid harm.</b><br>‘ talk with provider before taking OTCs or other prescription medications<br>‘ alcohol not recommended because of depressant effects, use sparingly if at all<br>‘ avoid operating hazardous machinery, incl automobiles, until certain how paroxetine effects cognitive/motor skills<br>‘ do not stop suddenly, talk with provider<br>‘ if more than the recommended dose has been taken, contact local poison control center or emergency room; symptoms of overdose include large pupils, severe drowsiness, severe nausea, vomiting, racing heartbeat and severe dry mouth | 1 2 3 4 5 6 7 8 9 |



|  |                   |
|--|-------------------|
| <b>5. Information includes enough detail for proper monitoring and interpretation of serious or frequently occurring adverse reactions.</b><br>' nausea and dizziness may be experienced at beginning of medication use but usually subsides<br>' other common side effects include: anxiety, drowsiness, dry mouth, weakness, decreased libido, changes in sexual function<br>' other side effects may occur, check with provider   | 1 2 3 4 5 6 7 8 9 |
| <b>6. Information includes proper storage instructions and general information.</b><br>' store at room temperature, away from excess heat or moisture and away from children<br>' includes disclaimer that this leaflet does not contain all possible information, provider can give additional info<br>' includes information stating that medicine should only be used by patient and not given to others; may request non-child resistant caps  | 1 2 3 4 5 6 7 8 9 |
| <b>7. Written information is unbiased in content and tone.</b><br>' neutral in content and tone<br>' does not contain promotional messages about product or compare to other brands (may compare chemical entities)<br>' fair balance re benefits/risks  | 1 2 3 4 5 6 7 8 9 |
| <b>8. Information is legible and readily comprehensible to most consumers.</b><br>' written clearly; avoids long sentences; avoids or explains polysyllabic terms<br>' layout calls attention to or makes it easy to locate important information, for ex., bullets, brief reinforcement separate from main text, bold-face type or box headings,<br>' printed in 10-point type or larger (this is 10-point type), w/ upper and lower case letters, good contrast, and adequate space between lines and paragraphs | 1 2 3 4 5 6 7 8 9 |
| <b>9. Written information is scientifically accurate.</b><br>' indication for use consistent w/ FDA labeling: treats depression, obsessive-compulsive disorder and panic disorder<br>' notes that it may be used for other purposes; communication with provider is encouraged<br>' general guide does not include info about non approved uses  | 1 2 3 4 5 6 7 8 9 |
| <b>10. Information is up-to-date and timely.</b><br>' includes publisher name and date of publication (not date printed for prescription use) or most recent revision<br>' and additional information is consistent with current FDA approved labeling or federally recognized compendia   | 1 2 3 4 5 6 7 8 9 |

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